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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA - OAKLAND DIVISION

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE,

Plaintiff,

vs.

ABBOTT LABORATORIES,

Defendant.

CASE NO. C 07-5702 (CW)

Related per December 5, 2007 Order to Case No. C 04-1511 (CW)

DEFENDANT ABBOTT LABORATORIES' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT OR, ALTERNATIVELY, SUMMARY ADJUDICATION ON DIRECT PURCHASER PLAINTIFFS' CLAIMS

AMENDED REDACTED VERSION FILED PURSUANT TO COURT ORDER

Judge: Honorable Claudia Wilken
Date: September 30, 2010
Time: 2:00 p.m.
Location: Courtroom 2 (4th Floor)

(Caption continued on next page)

SAFEWAY INC; WALGREEN CO.; THE KROGER CO.; NEW ALBERTSON'S, INC.; AMERICAN SALES COMPANY, INC.; AND HEB GROCERY COMPANY, LP, Plaintiffs, vs. ABBOTT LABORATORIES, Defendant.	CASE NO. C 07-5470 (CW) Related per November 19, 2007 Order to Case No. C 04-1511(CW)
RITE AID CORPORATION; RITE AID HDQTRS CORP.; JCG (PJC) USA, LLC; MAXI DRUG, INC D/B/A BROOKS PHARMACY; ECKERD CORPORATION; CVS PHARMACY, INC.; AND CAREMARK LLC, Plaintiffs, vs. ABBOTT LABORATORIES, Defendant.	CASE NO. C 07-6120 (CW) Related per December 5, 2007 Order to Case No. C 04-1511 (CW)
MEIJER, INC. & MEIJER DISTRIBUTION, INC.; ROCHESTER DRUG CO-OPERATIVE, INC.; AND LOUISIANA WHOLESALE DRUG COMPANY, INC., ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, Plaintiffs, vs. ABBOTT LABORATORIES, Defendant.	CASE NO. C 07-5985 (CW) (Consolidated Cases) Related per November 30, 2007 Order to Case No. C 04-1511 (CW)

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NOTICE OF MOTION AND MOTION

Abbott Laboratories ("Abbott") moves for summary judgment or alternatively summary adjudication of the claims asserted by the direct purchasers in Case Nos. 07-5470, 07-6120 and 07-5985 ("Direct Purchaser Plaintiffs" or "Plaintiffs"). Abbott is separately moving on the claims asserted by GlaxoSmithKline in Case No. 07-5702 ("GSK"). (To the extent that claims overlap, the two motions incorporate each other by reference.) This motion is brought on the grounds that there is no evidence of illegal monopolization or attempted monopolization. Additionally, there is no evidence that the Direct Purchaser Plaintiffs have suffered antitrust injury. This Motion is based upon this Notice, the attached Memorandum, the concurrently-filed Declarations of Scott C. Brun, Christopher J. Calamari, Michelle Friedland, Kevin W. Garren, and John Morris (including exhibits), and such material as is presented in Abbott's reply papers or at any hearing.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION & SUMMARY OF ARGUMENT

Plaintiffs' principal claim is that Abbott's comparative pricing of Norvir and Kaletra constituted predatory pricing under the discount attribution rule for bundled products set forth in *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008). Abbott previously argued that this claim fails under *John Doe 1 v. Abbott Labs.*, 571 F.3d 930 (9th Cir. 2009). Abbott renews those arguments but will not extensively re-brief them. Here, Abbott shows principally that (1) there is no evidence of monopoly power or a dangerous probability of monopoly power with respect to Kaletra, (2) the undisputed evidence shows that Kaletra is not a bundled product to which *Cascade*'s discount attribution rule applies; (3) there is no evidentiary support for a refusal to deal theory; and (4) the Direct Purchaser Plaintiffs lack antitrust injury.

Monopoly power. Monopoly power is the power "to control prices or exclude competition." *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 366 (9th Cir. 1988). The undisputed evidence shows that Abbott did not have the ability to control prices or exclude competition here. Since the introductions of Reyataz, Lexiva and Prezista, Abbott has been steadily losing market share, not excluding competitors. As the Ninth Circuit has held, "[i]n

evaluating monopoly power, it is not market share that counts, but the ability to *maintain* market share." *United States v. Syufy Enters.*, 903 F.2d 659, 665-66 (9th Cir. 1990) (emphasis in original). Further, "every firm can expand its sales quickly if the price is right." *Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325, 1335 (7th Cir. 1986); *see also Oahu Gas*, 838 F.2d at 366 (citing *Ball Mem'l*). Thus, a firm that does not have monopoly power can maintain or grow market share only through advantageous pricing. But Plaintiffs' central premise is that Kaletra was unable to maintain, let alone grow, market share—and that Abbott had to provide advantageous pricing to slow the pace of Kaletra's *losing* market share. This is fundamentally inconsistent with monopoly power. As the Ninth Circuit observed in *Syufy*, the plaintiff "would do better to plot the [market share] points on a graph and observe the pattern they form than to focus narrowly on [the defendant's] market share at a particular time." 903 F.2d at 666.

Moreover, a defendant that already has monopoly power has no reason to predatorily price. The premise of most predatory pricing is that monopoly power does not exist while the defendant's prices are predatory. Rather, in the typical case, monopoly power is hoped to be attained by the predatory pricing's driving out competitors. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225-27 (1993). Once the competitors are out, the defendant would have the power to raise prices without losing sales to the competitors—unless their products or new products would be unable to re-enter the market in a reasonable period of time. *Id.*; *accord Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) ("Predatory pricing occurs in two stages."); *Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1035 (9th Cir. 2001) ("once [the defendants] had market power, they would raise prices"). But the evidence is undisputed that Abbott did not drive out any competitors.

It is no answer that Plaintiffs have also alleged attempted monopoly. An attempt claim still requires evidence of a dangerous probability of attaining monopoly power. *Rebel Oil*, 51 F.3d at 1432-33. But the evidence is that, with each passing day, Abbott's market share has decreased. Abbott is not and never has been on the verge of driving any competitor out of the market. It is undisputed that Reyataz has overtaken Kaletra as the most prescribed boosted PI. The huge decline in Abbott's market share over the relevant period shows that any purported

attempted monopolization failed. *See Horst v. Laidlaw Waste Sys., Inc.*, 917 F. Supp. 739, 745 (D. Colo. 1996) ("as a matter of law, . . . there is no probability of success in monopolizing the relevant market since [defendant's] market share actually decreased during the relevant time period").

The question of whether Kaletra is a bundled product. The evidence is undisputed that Kaletra does not contain Norvir, the PI booster that Abbott sells separately, and therefore cannot be considered a "bundle" of Norvir and anything else. Of course, one of Kaletra's active pharmaceutical ingredients or "APIs", ritonavir, is the API in Norvir. But pharmaceutical products are not equivalent to their APIs, and Norvir is not Kaletra minus lopinavir. The creation of a pharmaceutical product centrally includes transforming the APIs into a dosage form that can be manufactured, distributed, stored, and safely and effectively administered in patients. This is an expensive and time-consuming process, utilizing teams of skilled scientists, and is integral to the success (and FDA approval) of the product. This was especially true for lopinavir and ritonavir, each of which belongs to the category of APIs that, for technical reasons, is extremely difficult to formulate into an effective drug product. Kaletra is thus fundamentally different from the discounted bundles that the Ninth Circuit discusses in *Cascade*—such as a hair care product supplier's selling a bottle of shampoo shrink-wrapped together with a bottle of conditioner or a hospital's discount to an insurer for making the hospital its preferred provider for primary, secondary and tertiary care. *See Cascade*, 515 F.3d at 893, 906 n.14. None involved the mere existence of a common ingredient in two products that are made by elaborate and individualized formulation and manufacturing processes of the sort involved in drug formulation. Kaletra is no more a bundle of Norvir and another product than raisin bread is a bundle of flour and raisins.

Refusal to Deal. The evidence disproves any claim that Abbott has priced Norvir so high that it is essentially unavailable. The data shows that Norvir is being purchased in huge and ever-increasing quantities; many more patients use Norvir as a booster than use Kaletra. Plaintiffs are left with only an "essential" refusal to deal theory that is at best a restatement of their *Cascade* theory that "the price of Norvir increased without a commensurate rise in the price of Kaletra," , making Kaletra comparatively cheaper. Docket No. 195, Case No. C 07-05702, at 14:24-25 (Jan.

12, 2010) ("MTD Order").

No Antitrust Injury. The Direct Purchaser Plaintiffs are in no position to complain about alleged predatory pricing. The cases uniformly recognize that, until and unless predatory pricing drives competitors out and allows recoupment, purchasers are economically benefitted, not harmed, by such pricing. *Advo, Inc. v. Phila. Newspapers, Inc.*, 51 F.3d 1191, 1200 (3d Cir. 1995) ("Predatory pricing schemes that fail at [or never reach] the recoupment stage. . . do not injure competition (*i.e.* they do not injure consumers) and so produce no antitrust injury."). As the Supreme Court has noted, "unsuccessful predation is in general a boon to consumers." *Brooke Group*, 509 U.S. at 224. The Direct Purchaser Plaintiffs' claims thus fail on the separate and independent basis that these Plaintiffs have not suffered antitrust injury. *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) ("*ARCO*").

For these and the other reasons shown below, this Court should enter summary judgment.

II. BACKGROUND

A. Abbott Obtained FDA Approval For The Norvir Soft Gel Capsule In 1996

The FDA approves drug products, not active pharmaceutical ingredients or "APIs." Declaration of Scott C. Brun ("Brun Decl.") ¶ 18. Drug products contain not just the API(s), but also excipients, principally solvents and stabilizers, in a formulation designed to optimize factors including chemical stability, provision of appropriate blood levels of the API, manufacturability, and pill burden. *Id*. ¶¶ 10, 25, 30.[1]

In 1996, the FDA approved a Norvir soft gel capsule to be used as a stand-alone protease inhibitor ("PI"). Declaration of Christopher J. Calamari ("Calamari Decl.") ¶ 13. Norvir's API is Ritonavir. Formulating Norvir had been extremely challenging. Brun Decl. ¶ 23. Ritonavir belongs to that class of APIs that are most difficult to formulate because they have both very low solubility and low permeability. *Id.* For this and other reasons, the ritonavir that could be included in a Norvir capsule was limited to 100 mg, although the recommended daily dose of

[1] Additional detail regarding Norvir and Kaletra's formulations, and the steps Abbott took to achieve them, are contained in the Declaration of John Morris.

ritonavir as a stand-alone PI was 1200 mg. *Id.*[2]

B. Kaletra Is A Co-Formulation Of Ritonavir And Lopinavir

In 2000, the FDA approved Kaletra, a soft get capsule co-formulation of lopinavir and ritonavir, the active ingredient in Norvir. Brun Decl. ¶¶ 4, 25. As with Norvir, finding the optimal formulation for Kaletra had been a difficult task. *Id.* ¶ 26. Often, the co-formulated product will require a different formulation than two standalone active pharmaceutical agents to achieve optimum *in vivo* performance, chemical and physical stability, manufacturability, and quality. *Id.* Formulation of Kaletra proceeded by trial and error—experimenting to optimize one property and then adjusting and reformulating to optimize others. *Id.* Analogous work must be done in formulating a drug product that contains only one API, but the work is significantly more complex in a co-formulated drug product because the attributes of two APIs must be monitored simultaneously and adjustments can affect each differently. *Id.* ¶ 27. Formulating Kaletra was especially complicated because, like ritonavir, lopinavir belongs to the class of APIs that is most difficult to formulate. *Id.*

Ultimately, Abbott formulated the Kaletra capsule to contain 33 mg of ritonavir and 133 mg of lopinavir. Abbott was constrained in the amount of ritonavir that could be included in a Kaletra capsule because the lopinavir that was also present would utilize much of the solvent ingredients, leaving less to dissolve the ritonavir. *Id.* ¶¶ 25-27. One of the more significant excipients was different in Norvir and Kaletra capsules (the co-solvent propylene glycol was used in Kaletra rather than ethanol). *Id.* ¶ 26.

C. Abbott Re-Priced Norvir But Not Kaletra

Although the FDA approved the Norvir capsule as a stand-alone PI, and that was its predominant original use, Abbott scientists discovered that a low dose of ritonavir keeps other PIs in patients' bloodstreams for extended periods, allowing use of less of those PIs. Declaration of Michelle Friedland ("Friedland Decl."), Ex. 1.[3]

[2] Drugs are often referred to based upon the milligrams of their APIs. For example, a reference to 100 mg of Norvir means that quantity of Norvir that contains 100 mg of ritonavir.

[3] Unless stated otherwise, all subsequent exhibit citations refer to exhibits to the Friedland Declaration.

Over time, doctors shifted from prescribing Norvir as a PI at 1200 mg per day to prescribing it as a low dose booster. Calamari Decl., ¶ 22 & Ex. 4, p. 24. Use of Norvir as a booster was of more value to patients because there were no other known boosters, Norvir appeared inferior as a PI to other PIs, and boosting allowed a patient to take less of the other PI—reducing side effects and often the total cost of the other PI treatment.[4] As one of Plaintiffs' medical experts testified, ritonavir "boosting has helped to improve patient lives, helped [make] more treatment options to be available for HIV treating clinicians and patients, and has helped to reduce the emergence of viral resistance." Ex. 2 (6/22/10 Richman Dep. 109:1-9).

In June 2003, Bristol Meyers-Squibb ("BMS") introduced Reyataz, a PI that is often prescribed with 100 mg of Norvir as a booster. Calamari Decl. ¶ 20. Norvir's most common daily dose quickly dropped to 100 mg.

It is undisputed that pharmaceuticals are priced based upon daily dose, not the milligrams of the API(s).[5] At Norvir's introduction, a daily dose was about $18. Although the shift to the boosting use caused Norvir's clinical value to increase, the price of Norvir's most common daily dose had decreased to $1.71 by late 2003. Calamari Decl. ¶¶ 22, 37. In December 2003, Abbott increased the price of a Norvir capsule from $1.71 to $8.57 for patients with private insurance (representing under 50% of patients taking Norvir). *Id.* ¶ 38. The price did not increase for patients on government programs like Medicare. *Id.* ¶¶ 39-41 & Exs. 30-31. Abbott also expanded its public access program that is designed to provide Norvir and other HIV drugs to uninsured patients for free. *Id.* ¶¶ 39-41 & Exs. 30-31.

It is undisputed that after the re-pricing, the most common daily dose of Norvir was 100 mg and cost $8.57. At 200 mg of ritonavir, Norvir's daily dose cost was $17.14. It is also

[4] For example, as of December 2007, Lexiva cost $40.80 per day at its unboosted dose of four 700-mg tablets. Calamari Decl. ¶ 47. With 100 mg of Norvir, the recommended daily dose of Lexiva is two 700-mg tablets. *Id.* The cost of that regimen is just $28.97 per day. *Id.*

[5] *See* Ex. 3 (1/29/10 Dolan Rep. ¶¶ 61-65) [redacted] Ex. 4 (6/18/10 Noll Dep. at 250:21-251:1) ("Q: Why do you believe that the comparisons that are most relevant are daily dose? A: Cause that's the relevant price to the consumer, to the buyer. The relevant price to the buyer is not how much does it cost per milligram but how much does it cost to control my disease."); Ex. 5 (5/5/10 Singer Rebuttal Rep. ¶ 10) (comparing prices of average daily doses); *id.* ¶ 49 ("[T]he dosage *level* is not a significant factor in the prices that pharmaceutical companies charge for their products.") (emphasis added).

undisputed that the price of Kaletra remained constant at approximately $18.80 from before December 2003 through the first quarter of 2005. *Id.* ¶ 44 & Ex. 5 at 21. Kaletra's price increased only moderately between 2005 and 2007, when it reached $23.40. *Id.*

D. Abbott Obtained Approval For An Improved Kaletra Formulation In 2005

In October 2005, Abbott obtained FDA approval of a tablet form of Kaletra manufactured with its patented "Meltrex" technology. Calamari Decl. ¶ 16. In this process, the API molecules are converted into an amorphous form dispersed evenly throughout a tablet, rather than remaining in the crystalline form that is in the soft gel capsules. Brun Decl. ¶¶ 29-30. This improves the ability of the drug to enter the bloodstream, as well as allowing storage at room temperature. *Id.* ¶ 29. Kaletra tablets are not rated by the FDA as strictly bioequivalent to the Kaletra capsule. *Id.* Also unlike either the Kaletra or the Norvir capsule, the Kaletra tablet does not need to be taken with food. *Id.* The excipients in the Kaletra tablet differ significantly from those in both the Kaletra soft capsule and the Norvir capsule. *Id.* ¶ 30.

As a result of the different forms of the APIs, excipients and manufacturing technology, Abbott was able to put 50 mg of ritonavir and 200 mg of lopinavir in each Kaletra tablet, thus reducing the Kaletra pill burden from 6 capsules to 4 tablets. *Id.* ¶ 30. Within four months, the tablet had entirely supplanted the capsule in the marketplace. Calamari Decl. ¶ 17 & Ex. 6, p. 4 [redacted]

E. Abbott Obtained Approval For An Improved Norvir Formulation In 2010

In February 2010, Abbott received FDA approval for a Norvir tablet. Brun Decl. ¶ 28. The Norvir tablet has many but not all of the advantages of the Kaletra tablet. (For example, unlike the Kaletra tablet, the Norvir tablet needs to be taken with food.) *Id.* ¶ 32.

Formulation of the Norvir tablet was not a matter of taking the Kaletra tablet formulation and removing the lopinavir. *Id.* ¶ 31. [redacted] *Id.* ¶ 33. Because Norvir contains more ritonavir as a percentage

of the pill's overall weight than Kaletra, and because ritonavir is even less soluble than lopinavir, there were significant challenges in developing a Norvir tablet that achieved appropriate stability and performance. *Id.* ¶ 32.

F. Boosted PI Sales Have Skyrocketed; Kaletra's Market Share Has Declined

Prescriptions of boosted PIs other than Kaletra have skyrocketed since the re-pricing of Norvir, as shown by the quadrupling of prescriptions for Norvir (which is now used almost exclusively as a booster) from 19,902 prescriptions in November 2003 to 96,095 in July 2009. Calamari Decl. ¶ 42 & Exs. 16 & 17 (Norvir Prescription Data).

Reyataz has almost quadrupled its boosted prescriptions from about 9,776 in November 2003 to over 56,000 in June 2009. *Id.* ¶ 26. Reyataz's sales consistently have exceeded the projections BMS made in 2002. Ex. 6 (BMS subpoena response). GSK's Lexiva was a new market entrant just starting to make sales in November 2003; in June 2009, it had over 15,000 boosted prescriptions. Calamari Decl. ¶¶ 25 & 26.

During this period, Kaletra's share of prescriptions for PIs boosted with ritonavir steadily declined, and Reyataz's and Lexiva's share grew. Ex. 7 (2/1/10 Noll Rep. Ex. 4c). As GSK's economic expert Dr. Noll's report shows, Reyataz has now overtaken Kaletra as the most prescribed boosted PI. *Id.* The only pause in Kaletra's share decline occurred immediately after Abbott launched the Kaletra tablet in October, 2005. *Id.*

Reyataz's and Lexiva's sales grew despite the fact that, as indicated in the chart in ¶ 44 of the accompanying Calamari declaration, the manufacturers of these drugs repeatedly increased their prices during this period. As Reyataz prescriptions were quadrupling, BMS raised the price of the average (boosted) daily dose by $6.45 (from $22.08 to $28.53) through 5 increases between December 2003 and August 2009. Calamari Decl. ¶ 46. GSK increased the price of Lexiva's average (boosted) daily dose by $6.80 (from $16.00 to $22.80) through 7 increases between December 2003 and August 2009. *Id.*

G. New Boosted PIs Have Entered the Market And A New Booster Is Expected

The number of boosted PIs also has increased since December 2003. In June 2005, the FDA approved Aptivus, a PI by Boehringer Ingelheim administered with 400 mg of Norvir daily.

Calamari Decl. ¶ 23. In June 2006, the FDA approved Tibotec's Prezista, a boosted PI administered with 100 mg of Norvir daily. *Id.* ¶ 24.

Two new drugs to boost PIs are also currently in development—Gilead Sciences' GS-9350 and Sequoia Pharmaceutical's SPI-452. Declaration of Kevin W. Garren ("Garren Decl.") ¶¶ 3-7 & Exs. 1-3; Brun Decl. ¶35; *see also* Ex. 10 (1/27/09 Shaefer Dep. 40:6-41:7) (GSK witness describing relevant research). In testing, GS-9350 has been shown to successfully boost Reyataz, and SPI-452 has been shown to successfully boost Invirase, Prezista, and Reyataz. Garren Decl. ¶¶ 4, 6-7; Brun Decl. ¶ 35. GS-9350 is expected to launch in 2013. Ex. 11.

H. There Is No Evidence That The Norvir Price Slowed PI Development

In discovery, Plaintiffs have at times pointed to efforts to develop new boosted PIs that have been stopped since December 2003, and certain of their experts appear to imply a causal link to the Norvir re-pricing. Ex. 7 (2/1/10 Noll Rep. at 132-33); Ex. 12 (5/5/10 Noll Rebuttal Rep. at 79-80); Ex. 5 (2/1/10 Singer Rebuttal Rep. ¶ 133). But experiments involving new drugs commonly fail; there is no admissible evidence tying any discontinuation to the Norvir price. The head of GSK's HIV franchise testified that [redacted] Ex. 14 (1/27/09 Hare Dep. 82:23-84:3). The only available information about the other companies are their public announcements attributing the terminations to poor clinical trial results or other problems.[6]

III. ARGUMENT

A. Plaintiffs' "Boosted Market" Monopolization Claims Fail

Abbott maintains that Plaintiffs' claims are precluded by *Doe* and *linkLine*, and the Court

[6] Triangle's statements about Mozenavir DMP450 and Roche's statements about RO033-4669 said that testing was halted because of disappointing clinical trial results. Exs. 15-17. Merck's statements said that L-756,423 was discontinued because of kidney toxicity. Ex. 15. Ambrilla/Procyon's statements said that MK-8122/PPL-100 was put on hold based on studies in healthy volunteers. Ex. 18.

Although Dr. Noll claims that all drugs currently under development "are either unboosted or are being developed in parallel with another PI booster," the publicly available evidence suggests that Narhex Life Sciences Limited is developing a PI, DG-17, that would be boosted by ritonavir. Ex. 19; Ex. 12 (5/5/10 Noll Rebuttal Rep. at 80). Sequoia Pharmaceuticals is also developing a PI, SPI-256, which could be boosted either by ritonavir or by the new booster Sequoia is developing, SPI-425. Ex. 20.

should so rule on summary judgment notwithstanding the Court's denying Abbott's motions to dismiss. As Abbott previously argued, *Doe* and *linkLine* require application of *Brooke Group*'s single-product predatory pricing test to the Direct Purchaser Plaintiffs' predatory pricing claims. Their claims fail because there is no allegation or evidence (i) that Abbott priced Kaletra below its cost of production or (ii) of a dangerous probability of recoupment.

Nonetheless, Abbott will not extensively re-brief those arguments here. Instead, the current brief shows that, even if *Doe* and *linkLine* do not control, Plaintiffs' claims for monopolization or attempted monopolization of what Plaintiffs define as the Boosted PI market fail based upon the absence of evidence to support other key elements of those claims.

1. There Is No Evidence Of Monopoly Power

Section 2 of the Sherman Act addresses *monopolies*. It is not a general regulation of business ethics. Nor does it target all conduct alleged to be anticompetitive. As the Supreme Court has explained, because unilateral conduct is unlike "concerted activity covered by § 1 [of the Sherman Act], which 'inherently is fraught with anticompetitive risk'," the antitrust laws are reluctant to target unilateral conduct. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). "For these reasons, § 2 makes the conduct of a single firm unlawful only when it actually monopolizes or dangerously threatens to do so." *Id.*

Monopoly power is defined as "the power to control prices or exclude competition" within the relevant product market. *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). As the Ninth Circuit has explained about monopoly power and the lesser but similar concept of market power:

> In order unilaterally to raise prices above competitive levels, the predator must obtain sufficient market power. A predator has sufficient market power when, by restricting its own output, it can restrict marketwide output and, hence, increase marketwide prices. Prices increase marketwide in response to the reduced output because consumers bid more in competing against one another to obtain the smaller quantity available. Without market power to increase prices above competitive levels, and sustain them for an extended period, a predator's actions do not threaten consumer welfare.

Rebel Oil, 51 F.3d at 1434 (citations omitted).

Many cases stress *Rebel Oil*'s concept that the defendant must be able to raise market-

wide prices for an extended period to justify a finding of monopoly power. "[U]ltimately, the court must resolve a practical question in every monopolization case: Is this the type of situation where market forces are likely to cure the perceived problem within a reasonable period of time?" *Syufy Enters.*, 903 F.2d at 663. If so, "a court ought to exercise extreme caution because judicial intervention in a competitive situation can itself upset the balance of market forces, bringing about the very ills the antitrust laws were meant to prevent." *Id.*

That extreme caution should be at its greatest when the monopolization claim is for predatory pricing. This is not just for the oft-stated reason that lower prices are usually pro-competitive and the courts should not be potentially encouraging higher prices. It is also more fundamentally because the very premise of a predatory pricing claim is typically that the defendant—far from currently being able to raise prices and restrain competitors from taking price sensitive customers' business—is able to increase its market share (if at all) only by more advantageous pricing. "A long-run strategy requires the predator to drive rivals from the market, or discipline them sufficiently so that they do not act as competitors normally should. . . . It then can collect the fruits of the predatory scheme by charging supracompetitive prices-prices above competitive levels." *Rebel Oil*, 51 F.3d at 1433-44. While the defendant is engaging in predatory pricing, there is the very antithesis of monopoly power. The defendant's monopoly power arises, if at all, from success in pushing rivals out and disabling them from quickly returning. *See Pool Water Prods.*, 258 F.3d at 1035 ("once [defendants] had market power, they would raise prices to supracompetitive levels").

The allegations here are an illustration of these principles. Plaintiffs allege that the introduction of Reyataz and then Lexiva and Prezista presented price and quality competition for Kaletra, and Abbott knew that it no longer had the ability to maintain Kaletra's prior market share. Plaintiffs allege that Abbott attempted to slow—although not stop—the erosion of Kaletra's share by creating a situation in which Kaletra was significantly cheaper than other boosted PI regimens. That is not monopoly power; it is the lack of monopoly power.

a. There Is No "Direct Evidence" Of Monopoly Power

Courts sometimes speak of "direct" and "indirect" proof of monopoly or market power.

"Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices." *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1475 (9th Cir. 1997) (internal quotation omitted); *accord Rebel Oil*, 51 F.3d at 1421. Here, there is no such evidence here.

First, there is no evidence that Abbott restricted its supply of Kaletra. There were no shortages of the product during the relevant period. Once again, Plaintiffs' theory of the case is that Abbott's goal was at all times to sell more Kaletra—that Abbott was worried that it was losing sales and share to the newly-introduced boosted PIs, and that Abbott offered advantageous pricing on Kaletra in order to try to capture more sales.

Likewise, Plaintiffs' theory of below-cost bundled pricing of Kaletra is fundamentally at odds with the notion that Abbott was selling Kaletra at supra-competitive prices. It cannot be the case that Kaletra's pricing was both below-cost and illegally supracompetitive. And the price increases for Kaletra over time have all been modest and in keeping with the price increases for other boosted PIs such as plaintiff GSK's Lexiva. Calamari Decl. ¶ 44. It is central to Plaintiffs' claims that Kaletra has cost much less than other boosted PI regimens. *See In re eBay Seller Antitrust Litig.*, No. C 07-01882, 2010 WL 760433, at *5 (N.D. Cal. Mar. 4, 2010) ("Evidence that eBay has raised prices over a period of years . . . proves nothing with respect to whether the prices are supracompetitive.").[7]

In sum, not only is there no evidence of restricted output or supra-competitive pricing of Kaletra during the period of alleged monopoly power, but Plaintiffs' position is also contrary to their theory of liability and therefore fails to satisfy the basic requirement that "[a]ntitrust claims must make economic sense." *Adaptive Power Solutions, LLC v. Hughes Missile Sys. Co.*, 141 F.3d 947, 952 (9th Cir. 1998).

[7] Plaintiffs' experts argue the relationship between Kaletra's price and marginal cost indicates *market* power; but they also acknowledge that every boosted PI—and every branded pharmaceutical—has market power by that measure. Ex. 21 (6/24/10 Singer Dep. 223:13-225:5); Ex. 22 (6/4/10 Leffler Dep. 191:1-192:6); *see also* 4/11/08 Order at 15 n.7 ("However, in the pharmaceutical industry, even in a crowded field of competing drugs, market prices will typically be well above marginal costs."). Further, the issue is monopoly power, not market power.

b. There Is No Circumstantial Evidence Of Monopoly Power

Plaintiffs also do not have circumstantial evidence of monopoly power. To demonstrate monopoly power circumstantially, a plaintiff must initially define the relevant market and show that the defendant has a dominant share of that market. *Rebel Oil*, 51 F.3d at 1434. But "market share is just the starting point for assessing market power." *Oahu Gas*, 838 F.2d at 366. "A high market share, though it may ordinarily raise an inference of market power, will not do so in a market with low entry barriers or other evidence of a defendant's inability to control prices or exclude competitors." *Id.* Here, Plaintiffs' evidence fails at every turn. Plaintiffs lack sufficient evidence to support their proposed definition of the relevant market, lack sufficient evidence that Abbott has a dominant share in such a proposed market, and lack sufficient evidence to negate the other evidence that Abbott does not have monopoly power in their proposed market.

(1) Plaintiffs Have Failed To Establish A Relevant Market

Antitrust plaintiffs bear the burden of establishing a relevant market, defined as "the group of sellers or producers who have the actual or potential ability to deprive each other of significant levels of business." *Rebel Oil*, 51 F.3d at 1434 (internal quotation omitted). Summary judgment is appropriate where the plaintiff fails to provide evidence that its market definition includes all competing products. *See Morgan, Strand, Wheeler & Biggs v. Radiology, Ltd.*, 924 F.2d 1484, 1489-90 (9th Cir. 1991) (summary judgment where plaintiffs failed to justify exclusion of certain physicians from the relevant market); *W. Parcel Express v. United Parcel Serv. of Am.*, 190 F.3d 974, 975 (9th Cir. 1999) (summary judgment where plaintiff "failed either to establish the proper boundaries of the relevant market or to demonstrate UPS's market share in that relevant market").

Here, Plaintiffs purport to define the relevant market as boosted PIs or some subgroup of boosted PIs. But Plaintiffs' own medical expert Dr. Richman testified to "a high degree of comparability between [NNRTIs] and a PI boosted with Norvir" and characterized these products as "equally appropriate alternative." Ex. 2 (6/22/10 Richman Dep. 145:1-148:11). Dr. Richman estimates that as many as *two-thirds* of treatment-naive patients can and do use NNRTIs and boosted PIs interchangeably. *Id.* at 76:20-77:9. The director of clinical research in GSK's HIV division, Dr. Shaeffer, likewise testified that, "based on the [DHHS] guidelines, and my treatment

experience and interaction, that yes, either a protease inhibitor or non nucleoside regimen are considered adequate therapy for . . . naive patients for initial therapy." Ex. 10 (1/27/09 Shaeffer Dep. 203:12-21). It is undisputed that NNRTIs and boosted PIs can deprive each other of significant levels of business.

Plaintiffs do not have any contrary economic evidence. Plaintiffs' economists do not perform any econometric analysis of demand elasticity to purport to show (contrary to what their physicians say) that there is not elasticity between NNRTIs and PIs. Instead, the economists merely contradict Plaintiffs' expert physician. The economists simply testify that, based upon their review of the medical literature, NNRTIs and PIs are not close enough substitutes to occupy the same relevant market. *See* Ex. 13 (2/1/10 Singer Rep. ¶¶ 85-86); Ex. 23 (2/1/10 Leffler Rep. ¶ 28); Ex. 7 (2/1/10 Noll Rep. at 16, 26-27).[8] The statements of these economists—devoid of econometric analysis—do not make it so. Expert opinions must be based on more than the *ipse dixit* of the experts. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); *see also Bailey v. Allgas, Inc.*, 284 F.3d 1237, 1247 (11th Cir. 2002) (summary judgment where economist conducted a "cursory assessment of reasonable substitutes" and rejected alternatives); *Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1369 (Fed. Cir. 2002) (summary judgment where plaintiff offered only "conclusory allegations" regarding relevant market); *Adams v. United States*, Civ. No. 03-0049, 2009 WL 2139710, at *2 (D. Idaho July 15, 2009) (excluding horticulturist's opinion interpreting insurance and government claim forms). Because Plaintiffs' economists do not offer *economic* analysis, their market definitions opinions are inadmissible and should be disregarded.

(2) The Direct Purchaser Plaintiffs' Absurdly Inflate Market Share

Without a reliable market definition, Plaintiffs cannot carry their burden of establishing that Kaeltra has a dominant market share. *See Rebel Oil*, 51 F.3d at 1434; *see also, e.g., E.I. du*

[8] The Direct Purchaser Class's economist identifies a boosted PI market limited to Kaletra, Lexiva, and Reyataz and an *alternative* boosted PI market "includ[ing] all PIs that are sometimes boosted with Norvir," but does not explain why one would be more or less appropriate than the other. Ex. 13 (2/1/10 Singer Rep. ¶ 84). GSK's economist identifies three alternative boosted PI markets, two of which only include some boosted PIs, and one that includes all boosted PIs. Ex. 7 (2/1/10 Noll Rep. at 66-67). The individual Direct Purchaser Plaintiffs' expert identifies a purported "boosted PI market" that includes all PIs that are boosted by Norvir as well as Norvir. Ex. 23 (2/1/10 Leffler Rep. ¶¶ 31-35).

Pont de Nemours & Co., 351 U.S. at 379, 400 (market share decreased from 75% to less than 15% when market definition was appropriately expanded). Even were there support for Plaintiffs' proposed markets, the Direct Purchaser Plaintiffs' experts also use utterly absurd methods of calculating market share. Unlike GSK's expert Dr. Noll, who simply adds up the numbers of prescriptions for each of the boosted PIs in his alternative markets, as he defines them, Ex. 7 (2/1/10 Noll Rep. at 5 & Ex. 4a), Drs. Leffler and Singer count each Kaletra prescription "as two Abbott prescriptions," thereby doubling Abbott's volume for each. Ex. 23 (2/1/10 Leffler Rep. ¶ 35 n. 60); Ex. 13 (2/1/10 Singer Rep. ¶ 89). Leffler and Singer further inflate Abbott's share by adding all *Norvir* prescriptions to Abbott's share of the boosted PI market. *See* Ex. 23 (2/1/10 Leffler Rep. ¶ 35); Ex. 13 (2/1/10 Singer Rep. ¶ 89). This triple-counting makes no economic sense and should be rejected. *See Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 468-69 (1992) ("If the plaintiff's theory is economically senseless, no reasonable jury could find in its favor, and summary judgment should be granted.").

Dr. Noll, who does not engage in these particular games, calculates that, [redacted] Ex. 7 (2/1/10 Noll Rep. at Ex. 4a). As this Court recognized in *Doe*, "To establish a prima facie case of market power, courts generally require a sixty-five percent market share." Docket No. 516, Case No. C 04-01511, at 10:14-16 (May 16, 2008) (citing *Kodak*, 125 F.3d at 1206). Thus, even assuming Noll's market definition which unjustifiably excludes some boosted PIs, Abbott had lost any purported monopoly power early in the relevant period. Indeed, it is undisputed that, by 2008, Reyataz had surpassed Kaletra as the most prescribed PI.[9]

(3) Kaletra's Declining Market Share Is Inconsistent With Monopoly Power

Regardless of Plaintiffs' market definition and share analyses, "[m]arket share . . . should not be equated with monopoly power." *Hunt-Wesson Foods, Inc. v. Ragu Foods, Inc.*, 627 F.2d

[9] In any event, even with his inflated market share analysis, Leffler has disclaimed any opinion that Kaletra monopolized the boosted PI market at any time. Ex. 22 (6/4/10 Leffler Dep. 262:25-263:9). Singer similarly does not opine that Kaletra had monopoly power at any point after Abbott's alleged below-cost pricing of Kaletra ended, which he places in 2007 (which, of course, is the only time period during which monopoly power would matter).

919, 925 (9th Cir. 1980). "Blind reliance upon market share, divorced from commercial reality, can give a misleading picture of a firm's actual ability to control prices or exclude competition." *Metro Mobile CTS, Inc. v. NewVector Commc'ns, Inc.*, 892 F.2d 62, 63 (9th Cir. 1989). "A mere showing of substantial or even dominant market share alone cannot establish market power sufficient to carry out a predatory scheme." *Rebel Oil*, 51 F.3d at 1439.

Thus, in *Metro Mobile*, the Ninth Circuit sustained a finding that a 100% share of the cellular telephone market was insufficient to establish monopoly power on the facts presented. 892 F.2d at 63. Likewise in *Syufy*, the Court held that the defendant did not have monopoly power even though it acquired 93% of the first-run Las Vegas movie theater business. 903 F.2d at 664. The Court held, "A high market share, though it may ordinarily raise an inference of monopoly power, will not do so in a market with low entry barriers or other evidence of a defendant's inability to control prices or exclude competitors." *Id*. (quoting *Oahu Gas*, 838 F.2d at 366). In *Rebel Oil*, the Ninth Circuit again affirmed summary judgment for the defendant on monopoly power notwithstanding the defendant's allegedly high market share. 51 F.3d at 1443.

In *Metro Mobile*, the evidence of the defendant's inability to control prices or exclude competitors was the lack of future barriers to entry into the cellular phone market, combined with the evidence that the defendant owed its original dominant share to the regulatory scheme. In *Syufy* the evidence included the defendant's consistently declining share from entry into the first-run movie market of a company that previously participated only in the second-run market.

In *Rebel Oil*, the evidence of the defendant's inability to control prices or exclude competitors was the fact that the other market participants were not output constrained—that is, the other gas station operators could sell more gasoline than they were selling, so that if Rebel Oil increased its prices, price sensitive customers could simply shift to other stations. As the Ninth Circuit wrote, "if rivals have idle plants and can quickly respond to any predator's attempt to raise prices above competitive levels, the predator will suffer an immediate loss of market share to competitors. In that instance, the predator does not have market power." 51 F.3d at 1441. Moreover, *Rebel Oil* held that "evidence of past output expansion may be used as a surrogate" for evidence of excess capacity and "[i]f there is undisputed evidence indicating that competitors

have expanded output in the recent past, or have the ability to expand output in the future, summary disposition may be appropriate." *Id.; accord Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1154 (9th Cir. 1997) ("Even if [defendant] has a high market share, neither monopoly power nor a dangerous probability of achieving monopoly power can exist absent evidence of barriers to new entry or expansion.").

Here, the number of market participants, the scale of any boosted PI market, and production by the other market participants have all dramatically expanded since 2003. At the same time, Kaletra's market share has steadily declined—even with the advantageous Kaletra pricing that Plaintiffs complain is so low as to be predatory. This is all evidence that Abbott cannot raise market-wide prices or exclude competitors. As the Ninth Circuit observed in *Syufy*, Plaintiffs "would do better to plot the [market share] points on a graph and observe the pattern they form than to focus narrowly on [Abbott's] market share at a particular time. 903 F.2d at 666.

First, it is undisputed that, in 2003, two new boosted PIs—Reyataz and Lexiva—entered the market. Calamari Decl. ¶¶ 20-21. In 2005 and 2006, two more boosted PIs—Prezista and Aptivus—entered the market. *Id.* ¶¶ 23-24. It is also undisputed that [redacted] *See* Ex. 7 (2/1/10 Noll Rep. Ex. 4c). In light of these products' entry and the prodigious expansion in their volume and market share, it cannot be seriously contended that Abbott has monopoly power in a "boosted PI" market. *See W. Parcel Express*, 190 F.3d at 976 (summary judgment and finding a lack of monopoly power where "during the time period in which [plaintiff] alleges antitrust injury, the market has actually expanded," and competitor's revenues increased by over 60%).

Plaintiffs' allegations of monopoly power are undermined by the undisputed fact that Kaletra's market share fell throughout this period of rapid expansion. Under Plaintiffs' own data for a market of all boosted PIs, Kaletra's share [redacted] Ex. 7 (2/1/10 Noll Rep. Ex. 4c). [redacted] *Id.* [redacted]

[redacted] Ex. 7 (2/1/10 Noll Rep. Ex. 4c). This steadily declining share for Kaletra is further evidence that Abbott did not have monopoly power in a purported boosted PI market. *See Syufy Enters.*, 903 F.2d at 666-69 (no monopoly power where evidence established a steadily declining, though still dominant, market share); *Laurence J. Gordon, Inc. v. Brandt, Inc.*, 554 F. Supp. 1144, 1156 (W.D. Wash. 1983) (concluding that plaintiff failed to establish monopoly power where defendant's "market share has been declining rapidly within the last few years," and the evidence indicated "vigorous" competition in the market).

A steadily declining market share also disposes of any claim for attempted monopolization, because it is fundamentally inconsistent with a dangerous probability of the defendant's obtaining monopoly power. *Horst*, 917 F. Supp. at 745 (finding "as a matter of law, that there is no probability of success in monopolizing the relevant market since [defendant's] market share actually decreased during the relevant time period").

(4) Competitors Face No Barriers to Expansion

There is also no evidence that Abbott's rivals would be unable to continue expanding if Kaletra's supply were reduced or its price increased. Indeed, given the financial resources of competitors such as GSK and BMS, it also cannot be seriously contended that those companies lack the ability to expand production. *See* Exs. 26-29 (showing GSK's and BMS's market capitalization of over $94 billion and $42 billion, respectively). Lack of barriers to expansion by existing competitors as a matter of law precludes a finding of monopoly power. *See Rebel Oil*, 51 F.3d at 1443 (summary judgment based upon conclusion that "the gasoline supply . . . is highly elastic and [] competitors could increase their output if [defendant] raised prices").

2. <u>Plaintiffs' Predatory Pricing Claims Fail Because Kaletra Is Not A "Bundle"</u>

The *Cascade* predatory pricing theory on which Plaintiffs rely applies only to bundled products. *Cascade* characterized "bundling" as "the practice of offering, for a single price, two or more goods or services that could be sold separately." *Cascade*, 515 F.3d at 894. The undisputed facts show that Kaletra is not a bundle. First, Kaletra is an integrated product, and integrated products are not bundles of "two or more goods," but rather are single products created by a

manufacturing process performed on their ingredients or inputs. Second, even if integrated products could be considered a bundle, which they cannot, Norvir is not a component of Kaletra.

All of the cases involving bundled discounting that the Ninth Circuit discussed in *Cascade* involved separate, independent products being packaged or sold together for a single price. *See* 515 F.3d at 893, 894, 895-96 & n.4. Kaletra is unlike any of those examples because it is a single, integrated product composed of several ingredients that have been formulated in particular proportions to achieve a particular pharmaceutical profile. As Plaintiff GSK's economist Dr. Noll himself explained, products that consist of ingredients or inputs cannot be thought of as bundles:

> Ingredients that are inputs to produce a final product involve the transformation of those ingredients. [The final product is] something completely distinct. And so I do not think it's useful to think of final products as bundles of their inputs.

Ex. 4 (6/18/10 Noll Dep. 281:11-15) As Dr. Noll went on to explain:

> the act of—of, say, manufacturing bread requires a separate kind of entrepreneurialness and creativity and productive act than simply buying flour, milk, and salt. You just don't take flour, milk, and salt and throw it all in the same bottle and say here's some bread. There's a separate creative act, a productive act, requiring distinct inputs to transform the inputs to an output.

Id. at 282:4-11; *see also* Ex. 21 (6/24/10 Singer Dep. at 53:18-54:8) (opining that a corn chip is a "single product," not a bundle of corn, corn oil, and salt); Ex. 22 (6/4/10 Leffler Dep. at 27:4-23) (corn chip is not a bundle of its ingredients). Kaletra is no more a bundle of its APIs than bread is a bundle of flour, milk, and salt.[10] Indeed, the Direct Purchaser Plaintiffs seem to recognize that Kaletra is an integrated product when they in their operative complaints describe Novir (really, ritonavir) as an "input or component" of Kaletra. Rite Aid Second Amended Complaint ("SAC") ¶ 17; Safeway SAC ¶ 19; Meijer SAC ¶ 17. This Court likewise previously wrote:

> As an initial matter, it is far from clear that Abbott's sale of Kaletra represents a bundled discount. Consumers do not purchase Kaletra because it provides them with a way to save on two products they would otherwise have to purchase separately. In fact, it is not readily apparent that Kaletra consists of two products at

[10] That the Ninth Circuit was thinking of bundles as joint sales of truly separate products is confirmed by the court's articulation of the discount attribution test, which refers to the "full amount of the *discounts* given by the defendant is allocated to the competitive product or products. . ." C*ascade*, 515 F.3d at 909 (emphasis added). The use of the word "discounts" suggests that the Ninth Circuit was thinking of multiple products, each of which would have a stand-alone price and an in-bundle price, with the difference between those prices being the "discount" on that product in the bundle.

> all -- ritonavir and lopinavir are combined in a single pill. Abbott does not offer lopinavir for sale independently of ritonavir; lopinavir is not licensed by the FDA for use except as part of Kaletra. Thus, it is not possible for Abbott to offer an actual discount on lopinavir when sold as part of Kaletra.

Docket No. 82, Case No. 07-05702, at 12 (Apr. 11, 2008).

Even if an integrated product like Kaletra could be considered a bundle under *Cascade*, which it cannot, Norvir is not a component of Kaletra. Ritonavir is in Kaletra, but ritonavir is a pharmaceutical input that can be formulated with other inputs to produce, alternatively, Norvir or Kaletra. Brun Decl. ¶¶ 22-33. This formulation process does not render Kaletra a "bundle" of Norvir and lopinavir any more than it renders Norvir a "bundle" of ritonavir and its excipient ingredients, or ritonavir a bundle of the molecules that are assembled to create it. Otherwise, *any* commercial product incorporating different inputs or ingredients would have to be treated as a "bundle," and the single-product test for predatory pricing would be subsumed by the exceptional rule stated in *Cascade* for bundled products. To use Dr. Noll's bread analogy, it would be baseless to call bread a bundle of flour and powdered milk just because bread and powdered milk are both made with milk. Plaintiffs have no better basis for claiming that Kaletra is a bundle containing Norvir just because both Kaletra and Norvir are made with ritonavir.

Notably, through most of the time period in question, Kaletra Meltrex was the form of Kaletra on the market—a tablet product containing an amorphous form of ritonavir that does not need refrigeration and is not taken with food—while Norvir was approved by the FDA and sold only in capsules that were a crystalline form of ritonavir in a liquid solution, requiring refrigeration and needing to be taken with food. *Id.* ¶ 29-30; Calamari Decl. ¶¶ 16-18. Further, the earlier Kaletra capsules were not simply Norvir plus lopinavir. The mere fact that both Norvir and Kaletra share a common API does not render Kaletra a "bundle" under *Cascade*.

In addition, there is no dispute that Abbott has never offered a PI containing lopinavir, the ingredient in Kaletra that is "boosted" by ritonavir, as its only API, *nor could* Abbott do so without creating and successfully testing a new formulation and then obtaining FDA approval. Brun Decl. ¶ 18. Such testing would by its nature be lengthy and expensive, and there is no evidence to suggest that the FDA ultimately would approve a solely lopinavir-based product. *Id.*

¶ 19. Kaletra is thus not a bundle under *Cascade* for the additional reason that lopinavir fails the threshold requirement that it "could be sold separately." *Cascade*, 515 F. 3d at 894.

Because Kaletra is a single, integrated product, Kaletra's pricing must be evaluated under *Brooke Group*'s single-product test. Plaintiffs offer no evidence to satisfy that test. To the contrary, Plaintiffs' experts' calculations demonstrate that Kaletra's price is well above Abbott's costs. Ex. 23 (2/1/10 Leffler Rep. ¶ 42); Ex. 13 (2/1/10 Singer Rep. Tabs. 2 & A3-8 (p. 34 & 88)).

3. <u>There Is No Evidence Supporting A Refusal To Deal Theory</u>

Due to the "uncertain virtue of forced sharing" and "the difficulty of identifying and remedying anticompetitive conduct by a single firm," the Supreme Court has been "very cautious" in recognizing exceptions to the baseline rule that "there is no duty to aid competitors." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408, 411 (2004) ("*Trinko*"). This Court nevertheless previously concluded that Plaintiffs adequately pled an effective refusal-to-deal. MTD Order at 15.

As a threshold matter, Abbott seeks summary judgment based on the same legal arguments advanced in its motion to dismiss. Abbott maintains that the facts of this case do not trigger antitrust liability under *Aspen Skiing*, *Trinko*, or *MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124 (9th Cir. 2004), because, among other reasons, Abbott did not refuse to sell Norvir to some at a price it was offering to others, and Abbott never sacrificed profits. But Abbott will not further re-brief those arguments here. Instead, Abbott shows here that the evidence precludes any claim of an actual refusal to deal, and that any claim for an "effective" refusal to deal is no more than a restatement of plaintiffs' claim that Abbott engaged in below-cost bundled discounting under *Cascade*.[11]

a. There Is No Evidence Of An Actual Refusal To Deal

There is no evidence that Abbott has ever refused to sell Norvir to anyone who wanted to purchase it, or that Abbott priced Norvir so high as to make the product unaffordable. Rather, the evidence shows that Norvir prescriptions have increased continuously and substantially ever since

[11] As noted above, Abbott also incorporates the arguments in the concurrently filed motion for summary judgment against GSK here, including the arguments about the refusal-to-deal claim.

the December 2003 price increase. *See* Calamari Decl., Exs. 16, 17 (Norvir prescriptions increased fourfold after November 2003, from 19,902 prescriptions to 96,095 prescriptions in July 2009). Meanwhile, the portion of patients who use Kaletra rather than other boosted PIs has been steadily declining since the Norvir price increase. Regardless of whether Plaintiffs could as a pleading matter viably allege a refusal to deal, this undisputed evidence precludes the claim that the price of Norvir was so high as to amount to an actual refusal to deal.

b. Plaintiffs' "Effective" Refusal To Deal Theory Is At Best Redundant

Plaintiffs are left to argue only that the Norvir price increase was an "effective" refusal to deal—that the increase put Abbott's competitors "in the untenable position of selling their boosted PIs at a price that could not compete with Kaletra," and that "[b]y setting such unattractive terms, Abbott essentially refused to deal with its competitors." MTD Order at 15. Once again, the undisputed evidence shows otherwise—Reyataz is now the most prescribed boosted PI. And, at best for Plaintiffs, this is just another way of saying that when one attributes all of the cost of Norvir to the ritonavir portion of Kaletra, the remaining amount of the Kaletra price is so low as to be predatory—in other words, that Abbott has engaged in below cost bundled pricing under *Cascade*'s "discount attribution" test.

To the extent that it might be argued that an "effective" refusal to deal claim could proceed even if Abbott's Norvir price is not too high to preclude patients from using it and even if Abbott's pricing of Kaletra is not "below cost" under the discount attribution test, *Cascade* itself shows that this argument must fail. *Cascade* explicitly held that "above-cost pricing will not be considered exclusionary conduct for antitrust purposes," 515 F.3d at 901, and rejected any test that would "ask[] the jury to consider whether the plaintiff has been excluded from the market, but [would] not require the jury to consider whether the plaintiff was at least as efficient of a producer as the defendant." *Id.* at 899. In other words, *Cascade* explicitly rejected the idea that there might be some other theory under which advantageous pricing can be challenged as exclusionary even though it is not below cost (under *any* measure) and not an actual refusal to deal.

B. Direct Purchaser Plaintiffs' Claims of Boosting Market Monopolization Fail

As separate claims, the Direct Purchaser Plaintiffs also allege that Abbott monopolized a PI booster market. *See* Rite Aid SAC ¶¶ 71-74; Meijer SAC ¶¶ 78-81; Safeway SAC ¶¶ 73-76. These plaintiffs claim that "Abbott deceptively induced rivals to forgo developmental alternatives and instead standardize around the use of Norvir for boosting purposes," later raising Norvir's price after rivals were "lock[ed] in." Rite Aid SAC ¶ 72; Safeway SAC ¶ 74; Meijer SAC ¶ 79.[12] Plaintiffs have no evidence to support these claims.

First, while Plaintiffs allege that the *low* pre-December 2003 Norvir price caused competitors to rely on Norvir and refrain from developing their own boosters (Rite Aid SAC ¶ 72; Safeway SAC ¶ 74; Meijer SAC ¶ 79), they do not allege that the earlier Norvir price was *below cost*, which precludes any claim based on the notion that the price of Norvir was too low. *See Brooke Group*, 509 U.S. at 223 ("the exclusionary effect of prices above a relevant measure of cost either reflects the lower cost structure of an alleged predator, and so represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting"). The fact that Abbott later increased the price of Norvir is of no import because "mere possession of monopoly power and the practice of charging monopoly prices does not run afoul of § 2." *Doe*, 571 F.3d at 934 (citing *Linkline*, 129 S. Ct. at 1118). Indeed, Abbott's price increase augmented others' incentives to create new booster drugs by "making the potential competition more attractive." *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 549 (9th Cir. 1991). Legally charging a monopoly price cannot be turned into illegal conduct by relabeling that conduct as the act of increasing a price.

Second, there is also no evidence that, as a result of Abbott's pre-December 2003 pricing of Norvir, competitors refrained from developing or introducing other PI boosters.

[12] Direct Purchaser Plaintiffs allege that if competitors (including GSK) had known Abbott would raise the price of Norvir, "GSK and other competitors would not have delayed or postponed efforts to develop alternative boosted PI drugs . . ." Rite Aid SAC ¶ 43; Meijer SAC ¶ 42; Safeway SAC ¶ 45. GSK does not join in these Plaintiffs' claims of boosting market monopolization, nor does GSK allege that it delayed production of alternative PIs despite its obvious incentives to make this allegation if it were true.

C. The Direct Purchaser Plaintiffs Have Not Suffered Antitrust Injury

To state a damages claim under the federal antitrust laws, private plaintiffs must show both that any alleged injury is causally linked to the alleged violation and that the alleged injury is "attributable to an *anticompetitive* aspect of the practice under scrutiny." *ARCO*, 495 U.S. at 334; *accord Rebel Oil*, 51 F.3d at 1433. The potentially anticompetitive aspect of predatory pricing is that the defendant will eliminate competitors from the market and then increase its pricing to supra-competitive levels. By contrast, until the elimination of competition, purchasers only benefit from alleged predatory pricing because they can purchase the goods or services at issue for less than if the defendant were not engaging in predatory pricing. As the Supreme Court has written, "unsuccessful predation is in general a boon to consumers." *Brooke Group*, 509 U.S. at 224. Unless competitors are driven out of the market, "predatory pricing produces lower aggregate prices in the market, *and consumer welfare is enhanced.*" *Id.* (emphasis added); *Advo*, 51 F.3d at 1200 ("Predatory pricing schemes that fail at [or never reach] the recoupment stage. . . do not injure competition (*i.e.* they do not injure consumers) and so produce no antitrust injury.").

Although the Supreme Court was writing about consumers, the same is true for direct purchasers who resell the products. Direct purchasers obtain lower prices from predation that does not drive competitors out of the market; direct purchasers are not harmed. "There can be no antitrust injury if the plaintiff stands to gain from the alleged unlawful conduct." *Am. Ad Mgmt., Inc. v. Gen. Tel. Co. of Cal.*, 190 F.3d 1051, 1056 (9th Cir. 1999). Accordingly, the Direct Purchaser Plaintiffs have not suffered antitrust injury and their damage claims fail as a matter of law. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 583 (1986) (manufacturers were not injured and therefore could not recover for a conspiracy to charge supra-competitive prices for electronics products because, "as [] competitors, respondents stand to gain from any conspiracy to raise the market price").

It is no answer that Plaintiffs allege an "effective" refusal-to-deal as well as predatory pricing. As shown, the effective refusal to deal theory adds nothing. Moreover, any injuries to the Direct Purchaser Plaintiffs from any refusal by Abbott to deal with competing manufacturers

would be insufficient to support antitrust standing because they would be indirect and purely derivative of the competitors' injury. *See Trinko*, 540 U.S. at 417 (Stevens, J., concurring) (injuries of customers who received poor service because of refusal to deal with AT&T "purely derivative of the injury that AT&T suffered," so customers lacked antitrust standing); *Int'l Bus. Machs. v. Platform Solutions*, 658 F. Supp. 2d 603, 610 (S.D.N.Y. 2009) (software distributor's injuries derivative of injuries to companies with whom IBM refused to deal).

The Direct Purchaser Plaintiffs also could not establish antitrust injury with respect to their Norvir monopolization claim—the claim that but for Abbott's conduct new PI boosters would have been developed. Without any evidence of such new boosters, a court is in no position to guess what such theoretical new products would have been and how they would have affected competition. As the Fourth Circuit has explained: "It would be entirely speculative and beyond the competence of a judicial proceeding to create in hindsight a technological universe that never came into existence. . . . It would be even more speculative to determine the relevant benefits and detriments that non-Microsoft products would have brought to the market." *Kloth v. Microsoft Corp.* 444 F.3d 312, 324 (4th Cir. 2006).

IV. CONCLUSION

For the foregoing reasons, this Court should grant Abbott's motion for summary judgment.

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